



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: NIKOLAI I. AFANASENKO ET AL. (PCT)
SERIAL NO.: 08/646,213 GROUP: 3302
FILED: MAY 7, 1996 EXAMINER: J. CLARK
FOR: DEVICE FOR TREATMENT OF PATIENTS WITH DISTURBED
POSTURE AND MOTOR ACTIVITY

DECLARATION UNDER RULE 132

ATTN: BOX FEE AMENDMENT
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Professor EVGENY SERGEEVICH BONDARENKO, M.D., declare that
I am Chairman of Infantile Neuropathology of the Academy of
Postgraduate Medical Training, Moscow, since 1979; and

that the following clinical tests (EXHIBIT A) were conducted
under my supervision:

EXHIBIT A

MEDICAL COMMENT

on clinical trials of the device
(therapeutic suit π K-92 "Adeli")
for treating patients with disturbed locomotorium

1. A clinical trial of the device π K-92 "Adeli" for treating
patients with disturbed locomotorium by a method of dynamic
proprioceptive correction was carried out from September, 1992, to
February, 1993, on the basis of the children's clinical
Psychoneurological Hospital No. 18 in Moscow.

The patients were under observation of the staff members of the chair of pediatric neurology of the Central Institute for Advanced Medical Training in the course of studies with students given a cycle of postgraduate advancement.

A total of 16 patients ages from 13 to 20 and affected by the various forms of infantile cerebral paralysis (ICP) were treated by the proposed device. Given below as an example are the diagnoses of some of the patients.

Female patient O.R-va, 20. Diagnosis: ICP in the hyperkinetic form, spastic-hyperkinetic dysarthria.

Female patient Yu.L-s, 16. Diagnosis: ICP, severe spastic diplegia, hyperkinetic syndrome, spastic-hyperkinetic dysarthria; status after operative treatment (bilateral Eggers operation).

Male patient A.B-kh, 18. Diagnosis: ICP, right hemiparesis, cerebellar syndrome.

Male patient, A.M-v. 16. Diagnosis: ICP, spastic diplegia, equinovarus.

Male patient D.A-v, 16. Diagnosis: infantile cerebral paralysis, spastic diplegia with the predominant affection of the right limbs, hyperkinetic syndrome, partial atrophy of the disks of the optical nerves, talipes equinus of the right foot.

Female patient O.-I-a, 13. Diagnosis: infantile cerebral paralysis, spastic diplegia following an operative treatment (surgery for bilateral bringing down of the straight femoral muscles, talipes equinoplanovalgus of both feet).

The patients were given a treatment course with the proposed device by daily sessions 30-40 min. long for 20 days. Concurrently the patients were given physical loads such as walking and isometric exercises applied to the pedal, pelvic, and trunk muscles.

As a control group, there was observed a group of 20 patients of the same hospital department, suffering from the various forms of ICP, who had been treated with the herefore-known generally adopted techniques and procedures used clinically both in this country and abroad.

2. The treatment results were judged by the following signs:

2.1 Correction of the already developed compensatory pathologic posture of the trunk and limbs depending on the formation of a specific form of ICP.

2.2 Augmenting of the muscle strength and a possibility of performing increased physical loads, that is, walking without earlier symptoms of fatigue and sensation of muscular weakness in the legs and trunk.

The Applicants would like to draw the Examiner's attention to the following:

known solutions were unable to satisfy the existing necessity in treating infantile cerebral paralysis (ICP) patents;

for a long period of time, experts were unable to solve said problem;

serious technical problems have been overcome while creating the invention;

the solution could not have been found as a result of mere logical conclusions or calculations;

technical prejudice and conservatism of experts have been overcome while creating the invention;

combination of structural elements gave a new and unexpected result in treating ICP;

the claimed invention, as tested and described in Exhibits A through G, makes it possible to advance considerably in developing the ICP rehabilitation.

2.3 Presence of initial and maintained psychological motivation for treatment.

3. Results of clinical trials of the proposed therapeutic device.

3.1. A positive effect as to the presence of all the aforementioned evaluating signs was observed in 12 out of 16 patients.

3.2. All the patients developed a distinctive increase in the muscular strength.

3.3. A marked correction of the posture was observed in 13 patients.

3.4. A reduced intensity of hyperkinesis and decreased flexural-pronator pathology in the arms and fingers under conditions of a complete absence of a goal-oriented correction of these disturbances.

3.5. Acute somatopathies may be pointed to as contraindications to the use of the proposed device.

4. Conclusion as the results of the clinical trials performed.

4.1. The proposed method for treatment of motor disturbances in children suffering from ICP and other diseases of the central nervous system with the aid of the device π K-92 "Adeli" resides in a fundamentally novel solution consisting in replacing previous static (passive) methods for correction of the pathologic positions of a limb (or part thereof) carried out by virtue of stage-by-stage plastering of the affected limb for a many-years period with a view to partially adapting this limb to supporting and a limited motion, by a functional (active) and one-stage correction of the position of not only the limbs but the whole body. The proposed method for treatment of motor dysfunctions secondary to ICP and other diseases of the central nervous system accompanied by disorders of the locomotorium with the aid of the proposed device allows for a single-step correction of the pathologic positions of the trunk and limbs. This in turn contributes to an increased activity of the muscles weakened by the disease and to stimulation of other muscles that are conducive to restoring a new motor stereotype. The results of the present method of treatment with the aid of the proposed device demonstrate a stable many-months therapeutic effect. The device allows for such a stereotype of posture and motion that approximates the normal physiological one.

4.2. Taking account of the above-stated positive result of clinical trials of the device for treatment of patients with infantile cerebral paralyzes and other diseases of the locomotorium, using the principle of correction of the proprioceptive afferent conduction, one can assess the results of

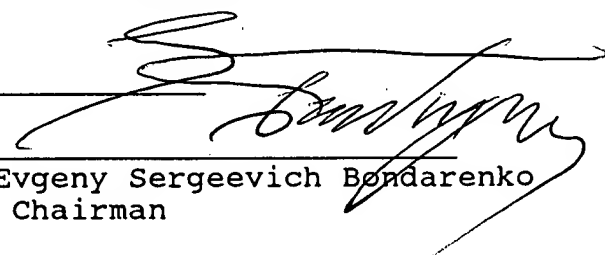
clinical trials of the device for bringing in medical practice for treating patients suffering from infantile cerebral paralyzes and other diseases of the locomotorium.

4.3. Application of the proposed device for accomplishing the objects of "treatment method" complies fully with the requirements of such method.

Thus, the device π K-92 "Adeli" can be recommended, on the grounds of its clinical trials, for use in medical practice and for a quantity production.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 11. 02. 98.


Name: Evgeny Sergeevich Bondarenko
Title: Chairman